REMARKS

I. Status of the Claims

Claims 1 and 4-10 were pending in the May 14, 2010 Office Action. Claims 4-10 are withdrawn. With this Reply, claim 1 is amended and claims 11-13 are newly added. The claim amendment and additions are made without prejudice or disclaimer, and introduce no new matter. Support for the claim amendment and new claim is found at least at page 32 of the specification as filed. Claims 1 and 11-13 are presented for reconsideration.

II. Rejections under 35 U.S.C. § 112, First Paragraph – Written Description

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, written description requirement. The Office Action asserts that the specification does not support a process of treatment for glomerular nephritis where streptococcus is not the causative agent. Applicants request reconsideration and withdrawal of this rejection in light of the claim amendments and the following discussion.

Claim 1 as amended is directed to

> A process for producing selective immune down regulation in a subject with rheumatic fever or glomerular nephritis that can result from infection with streptococcus, the process comprising the step of orally administering to said subject a reagent or a combination of reagents comprising components or fragments of streptococcus bacteria.

As such, the amended claim 1 specifies that the rheumatic fever or glomerular nephritis can result from infection with streptococcus. Applicants assert that claim 1, as well as new claims 11-13 are fully supported in the specification as filed, at least at page 32. The claims as amended therefore comply with the written description requirements of 35 U.S.C. 112, first paragraph. Accordingly, withdrawal of the written description rejection under 35 U.S.C. 112, is respectfully requested.

III. Rejections under 35 U.S.C. § 103

Claim 1 is rejected under 32 U.S.C. 103(a) as being unpatentable over Chen et al. (WO 96/39176) in view of Katz et al. (U.S. Patent No. 4,950,469).

The Office Action asserts that the cited references render the instant claims obvious because

> Chen et al. teach that oral tolerance to autoantigens can be used to treat antibody mediated autoimmune diseases wherein the disease involves antibodies which bind the pertinent autoantigen.... Chen et al. do not teach that the disease provoking antigen is streptococcus which is involved with the pathogenesis of rheumatic fever. Katz et al. teach that rheumatic fever involves an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues.... Katz teaches that agents which prevent binding of said antibodies could be used to treat rheumatic fever.

Office Action at page 4. Applicants request reconsideration and withdrawal of this rejection in light of the following comments.

Chen et al. teach inducing tolerance to autoimmune diseases by oral administration of autoantigens involved in the disease. However, Chen et al. do not teach or suggest the use of this treatment for any autoimmune disease induced by a pathogen. Additionally, Chen et al. teach only treatment with autoantigens, and not with antigens such as utilized in the process recited in the instant claims, which are not autoantigens (see below regarding the definition of "autoantigens"), but rather "components or fragments of streptococcus bacteria." Thus, Chen et al. do not teach or suggest the claim element in the instant claims that an autoimmune disease can be treated by oral administration of a foreign antigen, in this case components or fragments of streptococcus bacteria.

Katz et al. also do not teach or suggest treatment of an autoimmune disease using "components or fragments of streptococcus bacteria." While Katz et al. teach that "[r]heumatic fever is also believed to involve an autoimmune response to streptococcal antigens that are expressed by other tissues, especially cardiac tissue" (Katz et al., col. 6, lines 14-16), Katz et al. never acknowledge the fact that rheumatic fever is caused by an infection with streptococcus. In addition, there is no discussion in Katz et al. of the

possibility that rheumatic fever may be caused by direct exposure to streptococcal proteins. As discussed in previous responses, such a possibility was first raised by Quinn et al., 2001, Infect. Immun. 69:4072-4078 (published after the priority date of the instant application), who showed that streptococcal M protein induced valvular heart disease resembling rheumatic fever. Thus, it was not implicit to the skilled artisan at the time of filing that administration of a foreign protein could mimic induction of an autoimmune response derived from production of that protein during a pathogenic infection.

The Office Action also points to the Chen et al. definition of "autoantigen" at page 8, as including "...antigenic substances that induce conditions having the characteristics of an autoimmune disease when administered to mammals." The full passage from Chen et al. is

> "Autoantigen" **is** any substance or a portion thereof normally found within a mammal that invokes an immune response within an individual.... The term also includes antigenic substances that induce conditions having the characteristics of an autoimmune disease when administered to mammals.

(emphasis added). The above passage would be understood by the skilled artisan as defining an autoantigen as being normally found within a mammal, including antigenic substances that induce conditions having the characteristics of an autoimmune disease when administered to mammals. The passage does not indicate that the "antigenic substances that induce conditions having the characteristics of an autoimmune disease when administered to mammals" is an alternative definition of autoantigen, but rather as describing antigenic substances that are within the definition set forth in the first sentence. As such, the sentence "the term also includes..." would be understood as to be read in the context of the definition of autoantigen in the previous sentence as being normally found within a mammal. Such an interpretation of this passage of Chen et al. is further supported by the fact that nowhere in Chen et al. is it taught or suggested that such an autoantigen could include a foreign antigen. Indeed, the entire teaching of Chen et al. is that administration of the autologous antigenic substance is sufficient to tolerize the mammal to the autoantigen. The skilled artisan would therefore understand

from Chen et al. that the above definition of autoantigen would only include autologous antigens. As such, combining Chen et al. with Katz et al. would lead the skilled artisan to use the autoantigen (i.e., the cardiac tissue antigen that is recognized by autoantibodies) to tolerize the mammal as a rheumatic fever treatment, not streptococcal components or fragments as claimed.

In light of the above discussion, it is clear that neither Chen et al. nor Katz et al. teach or suggest that an autoimmune disease, in this case rheumatic fever or glomerular nephritis, can be treated with a component or fragment of streptococcus bacteria, as claimed. Since the cited combination of references do not teach or suggest that claim element, the obviousness rejection cannot be sustained. Withdrawal of the rejection under 35 U.S.C. 103(a) is therefore respectfully requested.

IV. Conclusion

In view of the foregoing remarks, Applicants respectfully request withdrawal of the rejections of record and passage of all claims to allowance.

The United States Patent and Trademark Office is hereby authorized to charge the extension of time and Request for Continued Examination fees, as well as any other fees required to maintain pendency of this application, to Deposit Account No. 05-1135.

If a telephone conversation would further the prosecution of the present application, Applicants' undersigned attorney requests that he be contacted at the number provided below.

Respectfully submitted,

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